duration on the most recent ECG.
Results: A total of 1,134 patients were actively enrolled in the program, of which 592 (52%) had EF ≤0.35. Out of this group, 62 (10%) were in atrial fibrillation or flutter and 55 (9%) had a preexisting pacemaker, which would have excluded them from entry into MIRACLE. The table lists the demographics and ECG characteristics of the remaining 475 patients who were in sinus rhythm.
Table. Demographics and ECG characteristics of 475 patients with EF ≤0.35.

	N (%)
Age <65 years	186 (39%)
≥65 years	289 (61%)
Male	317 (67%)
Left bundle block	76 (16%)
Right bundle block	32 (7%)
IVCD†	99(21%)
QRS <130ms	357 (75%)
≥130ms	118 (25%)

† QRS ≥110ms but neither left nor right bundle block.
Conclusion: Among 592 patients with symptomatic heart failure enrolled in a CHF care management program who have EF ≤0.35, 118 (20%) met the ECG entry criteria used in the MIRACLE study.

1090-19 **Rapid Detection of Atrial Tachyarrhythmia in Pacemaker Patients Using Home Monitoring**

Andreas Hartmann, Christoph Stellbrink, Jas Gill, Massimo Santini, Eckhart Wunderlich, Diran Igidbashian, St. Georg Hospital, Leipzig, Germany

Background: The current standard pacemaker follow-up scheme consists of regular clinical examinations every 3 to 6 months. This may entail a significant delay for the reaction to cardiac events, e. g. atrial tachycardia (AT), especially if asymptomatic. Home Monitoring (HM) may present a solution, as it offers frequent data transmission from the implant to the physician.
Methods: In a European multicenter clinical investigation, patients having indications for dual chamber pacing have been implanted with the pacemaker BA03 DDDR (Biotronik Inc.). The BA03 offers HM, i.e. automatically daily transfers a survey on mean ventricular rate, prevalence of intrinsic atrial and ventricular rhythm, atrioventricular conduction, and ventricular extrasystole via a GSM-net based mobile phone to a HM service center. The service center immediately sends the data to the physician via fax as so-called Cardio Report showing the latest data and the preceding data in tables and graphs. A patient may additionally trigger messages by applying a magnet. Primary endpoint of the study is the reliability of HM and will be presented elsewhere. We analyzed the clinical value of the transmitted data with respect to diagnosis of AT.
Results: Hundred twenty two patients have been included. Follow-up with HM lasted 82 ± 23 days (mean ± SD). 8425 HM messages are considered for the analysis. For 8 patients, AT were documented by conventional means (24-h long-term-ECG, symptoms). The onset of these AT could all be directly correlated to coincident changes of mean heart rate and atrioventricular synchrony in the HM data. However, similar changes were observed for 26 other patients. For 7 of these, the changes in HM parameters could be correlated to other clinically relevant events, like lead dislocation and undersensing. Ten of the remaining patients were known to have paroxysmal AT, although no event could be documented by conventional means during inclusion. For the other 9 patients, the origin is unclear.
Conclusion: Home Monitoring offers the possibility for improving follow-up of pacemaker patients by reducing reaction time to clinically relevant events. Sensitivity to AT is sufficient, however, specificity has to be improved.

1090-20 **A Randomized Study of Three Tilt Test Protocols With Long-Term Follow-Up by Implantable Loop Recorder**

David J. Farwell, Neil Sulke, Eastbourne General Hospital, Eastbourne, United Kingdom

Background: Head-Up tilt testing is an important tool in the diagnosis of syncope. We prospectively evaluated the clinical impact of three separate protocols. **Methods:** 214 patients with recurrent syncope were randomized to one of three tilt protocols, Drug Free, GTN and Adenosine, with upright carotid sinus massage. Tilts were terminated at the onset of syncope, when systolic BP reached 60 mmHg or in the presence of prolonged hypotension (>3mins systolic BP<80mmHg). Appropriate empiric therapies were commenced according to the result of the tilt test. 103 Patients were randomized to implantable loop recorder use & follow up, to cross correlate spontaneous syncopal events to tilt result, thus estimating the true sensitivity and specificity of tilt testing. Results were classified according to published criteria. **Results:** 13 patients recived pacemakers for class I indiacations.

Tilt Test Result

	Adenosine	Drug Free	GTN	All
Negative	75%	56%	24%	52%
Vaso vagal	15%	21%	55%	33%
CSH	10%	7%	3%	6%
Aut. Fail.	0	10%	2%	4%
Pseudseizure	0	1%	3%	1%
POTS	0	1%	3%	1%
Intolerant	0	1%	5%	2%

All three protocols gave similar VASIS classification results. We were able to correlate spontaneous syncope to tilt result in 34 patients. Sensitivities for all (combined protocols), adenosine, GTN and drug free protocols were 33%, 33%, 100% and 0% respectively. Specificities were 84%, 100%, 80%and 71% respectively. **Conclusions:** A diagnosis was made in 47% of patients with syncope using tilt testing. The GTN protocol gave the most true positive results with the best sensitivity and specificity.

ORAL CONTRIBUTIONS

803 Atrial Fibrillation Management

Monday, March 31, 2003, 9:15 a.m.-10:30 a.m.
McCormick Place, Room S102

9:15 a.m.

803-1 **The Canadian Registry of Atrial Fibrillation: Lack of Prognostic Differences Between Atrial Fibrillation and Atrial Flutter**

Paul A. LeLorier, Karin H. Humphries, Andrew Krahn, Stuart Connolly, Mario Talajic, Martin Green, Robert Sheldon, Paul Dorian, David Newman, Charles R. Kerr, Raymond Yee, George J. Klein, Boston Medical Center, Boston, MA, University of Western Ontario, London, ON, Canada

Background: The incidence of stroke is widely believed to be lower in atrial flutter (AFL) than in atrial fibrillation (AF) since the former represents an organized atrial rhythm. Convincing data to support this belief are not available. Methods: Between 1991 and 1996, 1097 patients were enrolled in Canadian Registry of Atrial Fibrillation (CARAF) from six major clinical centers throughout Canada. Of these, 94 patients with atrial flutter (AFL) and 787 with atrial fibrillation (AF) met inclusion criteria. Patients were followed annually for a median of 6.9 years and 61.7% were male. End-points were compared between patients with AFL and AF using Cox proportional hazards models for time-to-stroke and mortality adjusted for warfarin use and cardioversions. Results: The stroke rate was 1.3%/person-year in the AF group and 1.2%/person-year in the AFL group. The death rate was 3.5%/person-year in the AF group and 2.9%/person-year in the AFL group. The hazard ratio of AFL versus AF for stroke was 0.78 (CI 0.33 to 1.82) (p=0.56) and for mortality 0.71 (CI 0.42 to 1.20) (p=0.2). Age, history of stroke, diabetes, valvular heart disease, congestive heart failure, left ventricular hypertrophy and a hypokinetic ventricle were associated with increased mortality, regardless of rhythm. The same risk factors, with the exception of diabetes and congestive heart failure, were associated with stroke, regardless of rhythm. The use of warfarin was the same in both groups (p=0.1). Conclusions: Neither risk of stroke nor mortality differed between patients with AFL and AF. These results suggest the indications for anticoagulation should be the same for patients with either rhythm.

9:30 a.m.

803-2 **Determinants of Improvement of Quality of Life in Persistent Atrial Fibrillation: Data From the RACE Study**

Vincent E. Hagens, Adelita V. Ranchor, Eric Van Sonderen, Jan H. Kingma, Hans A. Bosker, Otto Kamp, Tsjerk Kingma, Harry J. Crijns, Isabelle C. Van Gelder, for the RACE Investigators, University Hospital, Groningen, The Netherlands

Background: Persistent atrial fibrillation (AF) may cause symptoms like fatigue, and dyspnea. This can impair quality of life (QoL). Treatment of AF with either rate or rhythm control may influence QoL. We sought to determine indicators of QoL changes during long-term follow-up.
Methods: In 352 patients included in the RACE study (rate versus rhythm control in persistent AF), QoL was assessed. Rate control patients (n=175) received negative chronotropic drugs, and oral anticoagulation (OAC). Rhythm control patients (n=177) underwent serial electrocardioversion, antiarrhythmic drugs, and OAC as needed. QoL was assessed using the Short Form (SF)-36 health survey questionnaire at baseline and end of study (EoS), after 2-3 years follow-up. Baseline and follow-up characteristics related to QoL improvement were determined.
Results: Mean age is 68 ± 9 years, present AF duration 1 month, 80% had underlying heart disease (49% class I, and 49% class II for heart failure), 70% had complaints of AF at inclusion. At the EoS, 10% versus 40% in rate versus rhythm control group were in sinus rhythm, respectively. Stepwise regression analysis showed that in the total group, sinus rhythm at EoS was related to a significant improvement of QoL (physical function-

ing, p=0.007, role limitation due to physical problems, p=0.047, role limitation due to emotional problems, p=0.036, and vitality, p=0.000), but not the type of randomized strategy. Also patients < 69 years (social functioning, p=0.03, and pain, p=0.044), AF duration < 1 month (social functioning, p=0.032), and those with complaints of AF at baseline (role limitation due to physical problems, p=0.041) showed QoL improvement.
Conclusion: Maintenance of sinus rhythm rather than the assigned strategy is an important parameter for improvement of QoL.

9:45 a.m.

803-3 The Detection of Left Atrial Thrombi in Patients With Atrial Fibrillation Were Associated With Thromboembolic Events During Long-Term Follow-Up

Karlheinz Seidl, Margit Vater, Monika Rameken, Andreas Brandt, Axel Droegemueller, Jochen Senges, Heart Center, Ludwigshafen, Germany

Aim of the study was evaluate the long-term outcome in patients (pts) with atrial fibrillation (AF), in whom a left atrial thrombus was detected by transesophageal echocardiography (TEE) in comparison to pts without thrombus.
Methods: In this single center observational study all pts were enrolled in this analysis if they were admitted to our hospital for the first time with the attention to cardiovert atrial fibrillation in sinus rhythm.
Results: Overall 447 pts were included in this study and in all pts TEE was performed. In 42 pts the left atrial thrombus was detected. 34 of these 42 pts (80%) were effectively anticoagulated with an INR (2 – 3). TEE was repeated in 31 of these 42 pts after 4 – 8 weeks. No left atrial thrombus was found in 20 pts. These 20 pts were then cardioverted. In the remaining 11 pts the left atrial thrombus was still present. During follow up of a median of 20 months 4 of these 42 pts had an embolic event (9.5%). All pts with a thrombus had an effective anticoagulation (INR 2-3) after discharge of the hospital. During the same follow up period 12/405 pts without a thrombus had a thromboembolic event (2.8%). Of these 405 pts 83% were effectively anticoagulated. Conclusion: Embolic event rate in pts with a left atrial thrombus is 9.5% in contrast to only 2.8% in pts without a thrombus during a median follow-up time of 20 months.

10:00 a.m.

803-4 An Endovascular Approach to Stroke Prevention in Atrial Fibrillation: Results of the Multicenter PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) Feasibility Trial

Mark Reisman, William Gray, Horst Sievert, Paul Kramer, Peter C. Block, Carlo DiMario, Antonio L. Bartorelli, Paolo Della Bella, Heyder Omran, Athena Poppas, David O. Williams, Allan Skanes, Bernhard Meier, Toshiko Nakai, Michael D. Lesh, Swedish Heart Institute, Seattle, WA

Background: Thromboembolism due to atrial fibrillation (AF) is a frequent cause of stroke. During non-rheumatic AF, thrombus originates predominantly in the left atrial appendage (LAA). Anticoagulation (warfarin) therapy has demonstrated a two-thirds reduction in stroke risk. In pts suboptimal for warfarin therapy, occlusion of the LAA may significantly reduce the risk of thromboembolism. The purpose of this phase one study is to determine the safety and feasibility of the PLAATO™ procedure in high risk AF pts who are poor warfarin candidates.
Methods: Patients were enrolled who have chronic or paroxysmal AF and are at high risk for stroke based on the presence of congestive heart failure, diabetes mellitus, hypertension, history of stroke/transient ischemic attack (TIA), or high-risk echo findings with transesophageal echocardiography (TEE). Patients with existing LAA thrombus were excluded. The PLAATO system consists of a self-expanding cage covered with ePTFE delivered through a 12Fr transseptal sheath specially designed to access the LAA. Device placement is guided by fluoroscopy and TEE.
Results: A total of 56 pts, age 70±7 yrs (M/F=36/20) were enrolled. Device deployment was successful in 55/56 pts (98%). One pt had a groin complication during venous access so the procedure was aborted. Seventeen of 56 pts had a history of Stroke/TIA and 26/56 pts had high risk echo findings defined as low LAA emptying velocity or spontaneous echo contrast in the LAA. Devices were oversized by 20%-50% of LAA diameter. Procedure time was 76±30 min. Procedural complication occurred in 6 pts (10%) and included 3 pericardial effusion, 2 groin hematoma and 1 false aneurysm. Clinical follow-up at 6 mos (33 pts) included 1 death (not device related) and 0 CVA's. TEE follow-up at 6 mos (16 pts) confirmed stable implant position with a smooth atrial-facing surface. In one pt, a smooth echodense layer was seen along device surface at 1 and 6 mos, which resolved at 9 mos: no clinical events have occurred in this pt.
Conclusions: Transcatheter occlusion of the LAA with a novel implantable device appears feasible and safe. Whether or not it confers protection against stroke will be predicated from our long term clinical follow-up.

10:15 a.m.

803-5 Sinus Rhythm Control in Atrial Fibrillation: Outcomes From a Controlled Long-Term Ablation Study

Carlo Pappone, Salvatore Rosanio, Giuseppe Augello, Alessia Pappone, Patrizio Mazzone, Simone Gulletta, Mario Pittalis, Gabriele Paglino, Gabriele Vicedomini, San Raffaele University Hospital, Milan, Italy

Background: Atrial fibrillation (AF) is associated with a 1.5- to 1.9-fold mortality risk and 2.6- to 4.5-fold risk of stroke as compared with subjects in sinus rhythm (SR). Circumferential pulmonary vein ablation (CPVA) has emerged as safe and effective treatment for curing atrial fibrillation (AF). However only limited evidence exists to support a clinical benefit of maintaining SR beyond preventing symptoms.
Objective: To test retrospectively the hypothesis that long-term maintenance of SR translates in prolonged survival and reduced morbidity.
Methods: 589 ablated patients (pts) (mean age, 65 ± 9 yrs; chronic AF, 21%; mean AF duration, 2.9 yrs) were compared with 582 (65 ± 10 yrs; chronic AF, 19%; mean AF duration, 2.1 yrs) who were given antiarrhythmic drugs for preventing recurrent AF, between January 1998 and March 2001. For both groups follow-up, including serial visits, 24-hour Holter recordings and echocardiograms, began at hospital discharge, ended in March 2002, and averaged 854 days.
Results: At final analysis, 20% of ablated patients and 58% among medically treated have had their first relapses (P<0.001, by log-rank statistic). Cox proportional hazard model revealed ablation was 3-fold as efficacious as drugs in preventing recurrences (hazard ratio [HR], 0.31, 95%CI 0.22 to 0.47, P=0.002). When entered as a time-dependent variable into the Cox model, maintenance of SR, was associated with substantial reductions in the risk of death (HR, 0.46, 95%CI 0.22 to 0.68; P<0.001) and major morbidities mainly due to heart failure and stroke (HR, 0.45, 95%CI 0.21 to 0.57; P<0.001), either considering all patients or the two treatment groups separately (ratio of HRs 0.99, P=0.78).
Conclusion: These results question the conclusions of the AFFIRM trial about the lack of benefit of SR control over rate control by drugs in AF pts, and substantiate the claim that obtaining SR is more important than using SR as a marker of good health. That SR resulted as a strong prognostic determinant reinforces the concept that, AF, by itself or as hastening factor, may cause excess mortality and morbidity. Thereby, its prevention and suppression should always be pursued.

ORAL CONTRIBUTIONS

814 Electrocardiographic Predictors of Cardiac Mortality

Monday, March 31, 2003, 11:00 a.m.-12:15 p.m.
McCormick Place, Room S404

11:00 a.m.

814-1 Lack of QT Prolongation With Amiodarone Increases Arrhythmic Risk

Peter Smetana, Esther Pueyo, Katerina Hnatkova, Marek Malik, St. George's Hospital Medical School, London, United Kingdom

Background: The superior anti-arrhythmic efficacy of amiodarone (A) is partly explained by an almost heart rate independent prolongation of the QT interval. Thus A treated patients with reduced QT prolongation might be at higher arrhythmic risk. We therefore investigated QT intervals at different heart rates in A and placebo (P) treated post-myocardial infarction (MI) patients. **Methods:** In 24-hours recordings from 866 EMIAT patients (462 A, 404 P) obtained 1 month after randomisation, QT intervals were obtained automatically by using the Pathfinder software (Reynolds Med Tec). QT values were averaged over 10-ms RR interval bins from 550 to 1150 ms in each recording. Results were compared between survivors (SUR, circles) and victims of non-arrhythmic (NAD, dots) and arrhythmic death (AD, triangles) both in A (left panel) and P (right panel) groups. **Results:** As expected QT intervals were significantly longer at all investigated RR interval bins on A. However, whereas there was no significant difference in the QT intervals between SUR, NAD and AD patients in the P arm (SUR vs AD at 540-550 ms: 338± 25 vs 337± 23 ms, p=ns and at 1140-1150 ms: 428± 40 vs 417± 48 ms, p=ns), QT intervals in the A arm were shorter in AD patients than in SUR at all RR interval bins (SUR vs AD at 540-550 ms: 349± 24 vs 346± 20 ms, p=ns and at 1140-1150 ms: 469± 40 vs 423± 20 ms, p=2x 10^{-4}).
Conclusions: Reduced prolongation of QT interval by A increases the risk of AD in post-MI patients.